REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 1, 13 and 14 have been amended to further clarify Applicants' invention. No new matter has been added.

I. Rejections Under 35 U.S.C. § 112

Claims 1-7, 9 and 13 have been rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse this rejection.

The Examiner has stated, *inter alia*, that there is no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change and the nature and extent of changes that can be made in these positions.

The ultimate question is whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the art to practice the claimed invention without undue experimentation. See, e.g., *Ex Parte Foreman*, 230 U.S.P.Q. 546, 547 (PTO Bd. App. & Int. 1986). That some experimentation is necessary does not preclude enablement unless the amount of experimentation is unduly extensive. See, e.g., *U.S. v. Telectronics, Inc.*, 8 U.S.P.Q. 2d 1217, 1222 (Fed. Cir. 1988).

Applicants submit that the specification provides guidance to enable one skilled in the art. For example, page 3, lines 10-17, of the specification states that up to 10 amino acids may be deleted, substituted or inserted relative to the native protein wherein the function of the modified protein is not "significantly affected" relative to the native protein (i.e., the modified protein can act as a co-activator or human androgen receptor and human estrogen receptor β). "Significantly affected" is defined on page 6 as meaning that the modified protein has at least 50% of the activity as the native protein. This determination is routine and does not constitute undue experimentation.

With regard to the substitutions that can be made, pages 3-8 of the specification provides guidance here too. Specifically, page 5 (and the table on page 7) discusses the conservative substitutions that can be made in the protein without significantly affecting the

function/activity of the modified protein. Again, determining the activity or function of the modified protein relative to the native protein is routine and does not constitute undue experimentation.

Thus, one of ordinary skill in the art could readily ascertain the possible biologically active derivatives of SLIM3, which have utility in the invention. It is conventional practice in the art to make various derivatives or modifications of a native co-activator protein, e.g., SLIM3, for the purpose of identifying agents which can affect the interaction of the co-activator protein with a target protein, e.g. androgen receptor or estrogen receptor β.

The Examiner has failed to provide any reasons or evidence why one of skill in the art would not be able to utilize the specification and conventional methods in the art to create derivatives and to ascertain the biological activity of such derivatives/modifications without having to revert to undue experimentation.

The Examiner has stated that the specification fails to provide specific guidance regarding the regions of SLIM3 that are functionally important and how any given set of changes will affect that function. Applicants respectfully disagree.

As discussed above, creating mutants or modified proteins is common and well known in the art. It is not necessary to determine the "functionally important" regions of a protein when modifying a protein. If a particular modification renders the protein non-functional, then that modified protein (or modification) is not desired.

Thus, based on the disclosure of the specification and what is known in the art, the skilled artisan will be able to practice the invention as claimed.

Accordingly, applicants respectfully request that the rejection of the claims under §112, first paragraph is withdrawn.

Claim 13 has been rejected under 35 U.S.C. § 112, first paragraph.

To comply with the written description requirement, it is not necessary that the specification describe the claimed invention in *ipsis verbis*. All that is required is that it reasonably convey to persons skilled in the art that, as of the filing date, the inventor had possession of the claimed subject matter. *In re Edwards*, 196 U.S.P.Q. 465 (C.C.P.A. 1978). Further, applicants are not required to provide an example for each protein that falls within the claim.

The Examiner has acknowledged that applicants are in possession of the SLIM3 protein. However, the Examiner alleges that applicants are not in possession of "allelic variants" of SLIM3.

The Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, first paragraph, state that "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species [there may be situations where one species adequately supports a genus] by actual reduction to practice, reduction to drawings or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics . . . ." Further, the PTO training materials for Written Description provide examples of claims that satisfy the written description requirements set forth in § 112. For example, a claim drawn to variants of a disclosed protein sequence does not violate the written description requirement if the claim recites that the variants are structurally similar to the disclosed sequence and possess the same function as the disclosed protein (see Example 14 for proteins and Example 9 for nucleic acids). Further, in Example 14, the procedure for determining if the variants possess the claimed function was described in the specification.

In the subject application, applicants claim proteins that have the same functional characteristics as the disclosed SLIM3 protein (i.e., the claimed protein functions as a co-activator of androgen receptor and estrogen receptor β). In addition, the claimed variants are at least 90% homologous to SLIM3. Thus, applicants have satisfied the written description requirement, in accordance with the PTO's own Guidelines, by disclosing relevant identifying characteristics (i.e., by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics). Therefore, in view of the foregoing, one of skill in the art would conclude that applicants were in possession of the claimed invention.

Accordingly, applicants respectfully request withdrawal of this rejection.

Claims 1-7 and 9 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse this rejection.

The Examiner has stated that the claims nor the specification define the biological activity of SLIM3. Applicants respectfully disagree.

Page 4 of the specification describes SLIM3 as a co-activator for androgen receptor and estrogen receptor β. However, to expedite prosecution and not to acquiesce to the Examiner's rejection, applicants have amended claims 1 and 13 to recite this function.

Accordingly, applications respectfully request withdrawal of this rejection.

II. Rejections Under 35 U.S.C. § 102

Claims 1-7 and 9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chang et al. (U.S. Patent No. 5,789,170). Applicants respectfully traverse this rejection.

The claimed invention relates to, *inter alia*, methods for screening for agents that affect the interaction between SLIM3 and the proteins to which it specifically binds (e.g., the androgen receptor or the estrogen receptor β).

Chang et al. does not describe the claimed method of identifying agents that regulate the transcriptional activating activity of human androgen receptor and/or estrogen receptor β. The ARA_{70} protein disclosed by Change et al. is specific for activating the androgen receptor and has very little, if any, effect on other steroid receptors such as the estrogen receptor (see column 6, lines 25-33, of Chang et al.). Further, regarding the "biologically active derivative" and "allelic derivative" of SLIM3 in claims 1 and 13, respectively, the ARA_{70} protein of Chang et al. is not at least 90% homologous to SLIM3 and does not function as a co-activator for androgen receptor and estrogen receptor β (claim 1) or maintain at least 80% of the activity of unmodified SLIM3 (claim 13).

Therefore, because Chang et al. does not teach each and every element of the claimed invention, this reference cannot anticipate the claimed invention.

Accordingly, applications respectfully request withdrawal of this rejection.

Claims 1, 3, 9, and 13-14 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Culig et al. Applicants respectfully traverse this rejection.

Culig et al. relates to androgen receptor activation in prostate tissue by various growth factors (e.g., insulin-like, keratinocyte and epidermal growth factors). Specifically, the purpose of the study was to determine whether certain known growth factors could directly

stimulate/activate the androgen receptor-CAT construct (see the abstract of Culig et al.-IGF-I, KGF and EGF directly activate the androgen receptor).

The claimed method identifies proteins that affect the binding of SLIM3 (or a derivative thereof) to its binding partners (e.g., androgen receptor and estrogen receptor β). Culig et al. does not disclose or even suggest SLIM3, which is a co-activator of androgen receptor and estrogen receptor β.

Furthermore, Culig et al. does not describe or suggest a protein that is at least 90% homologous to SLIM3 and functions as a co-activator for androgen receptor and estrogen receptor β (claim 1) or maintains at least 80% of the activity of unmodified SLIM3 (claim 13).

Therefore, because Culig et al. does not teach each and every element of the claimed invention, this reference cannot anticipate the claimed invention.

Accordingly, applications respectfully request withdrawal of this rejection.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney or agent concerning such questions so that prosecution of this application may be expedited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: October 28, 2003
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